Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0685520	01/07/2020
Name of Provider or Supplier	**Street Address, City, State**	
Coliseum Pediatric & Adolescent Care	145 N Crest Boulevard, Macon, GA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	On January 31, 2020, an off site followup review was completed. The report revealed that corrective action was found to be acceptable and corrected. The facility is now in compliance with with all regulations surveyed.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) records and staff interview , the laboratory testing personnel (TP) and/or lab director (LD) failed to attest that PT samples were tested in the same manner as patient specimens. Findings include: 1. Review of PT attestation statements for 2018 and 2019 reveals the TP nor LD signed the statements for 2018 testing events #2 & #3 and 2019 testing events #1 & #3. 2. Review of PT attestation statements for 2019 reveals the LD failed to sign the statement for testing event #2. 3. Interviews with staff #2 and #3 (CMS 209 form) on 1/7/2020 at approximately 230 pm in the lab, confirmed the attestation statements did not have all the required signatures.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed

	by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) records and staff interview, the laboratory failed to ensure PT original documents were maintained. Findings include: 1. Review of PT document records reveals the lab did not retain original documents for 2019 testing event #3. 2. Interviews with staff #2 and #3 (CMS 209 form) on 1/7/2020 at approximately 230 pm in the lab, confirmed the documents were not present at the time of the survey.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of personnel competency assessment records and staff interview, the Technical Consultant failed to include the six required competency assessment criteria when evaluating competency on 3 of 3 testing personnel for testing performed on the CellDyn Emerald hematology analyzer for 2018 and 2019. The findings include: 1. Review of testing personnel competency assessment records for 2018 and 2019 on 3 of 3 employees revealed the assessment did not include the six competency assessment criteria required by CLIA. 2. Interview with staff #3 (see CMS 209) in the lab on January 7, 2020 at approximately 230 PM confirmed all employees perform testing on the CellDyn Emerald hematology analyzer and annual competency assessments did not contain the six required competency assessment criteria.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on CellDyn Emerald maintenance review and staff interview, the lab failed to perform/document maintenance per the manufacturer manual. Findings include: 1. Review of CellDyn Emerald maintenance documents of January, February, June, August, and October 2018 reveals Monthly Bleach Cleaning was not performed /documented. 2. Review of CellDyn Emerald maintenance documents of January, April, June, and September 2019 reveals Monthly Bleach Cleaning was not performed /documented. 3. Interview with staff #2 and staff #3 (CMS 209 form) on 1/7/2020 in the lab at approximately 230 PM, confirmed the monthly maintenance had not been performed/documented.

D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of hematology calibration documents and staff interview, the laboratory failed to calibrate the CellDyn Emerald analyzer at least every 6 months. Findings include: 1. Review of calibration documents reveals the CellDyn analyzer was calibrated: 3/8/18, 11/26/18, and 12/19/18. Span between calibration on 3/8/18 and 11/26/18 is 8 months. 2. Review of calibration documents reveals the CellDyn analyzer was calibrated: 3/24/19 and 12/9/19. Span between calibration on 3/24/19 and 12/9/19 is 9 months. 3. Interview with staff #3 (CMS 209) in the lab on January 7, 2020 at approximately 3 PM confirmed the time spans between calibrations. **Repeat deficiency**
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on lab report review and staff interview, the laboratory failed to include all the required information on the in-house laboratory test reports. Findings include: 1. Review of in-house test report #041203 reveals the lab name and address was not on the test report. 2. Review of in-house test report #041203 reveals the reference range or units of measurement was not on the test report. 3. Interview with staff #3 (CMS 209 form) on 1/7/2020 in the lab at approximately 230 PM, confirmed the missing information from the in-house laboratory test reports.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

	test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's Proficiency Testing (PT) records and staff interview, the laboratory director (LD) failed to ensure PT results were reviewed upon receipt from the PT agency. Findings include: 1. Review of PT records for 2018 and 2019 reveals the laboratory did not review results for 2018 Events #2 & #3 or 2019 event #1. 2. Interviews with staff #2 and #3 (CMS 209 form) on 1/7/2020 at approximately 230 PM pm in the lab, confirmed results did not have review documentation.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) competency documents and staff interview, the technical consultant (the lab director) failed to perform semiannual competency on all new testing personnel. Findings include: 1. Review of TP competency documents reveals staff #4 (CMS 209) with a training date of 1/21/19 and no 6 month competency record on file. 2. Interview with staff #3 (CMS 209) in the lab on January 7, 2020 at approximately 230 PM confirmed staff #4 (CMS 209) did not have a 6 month competency done.